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Atty. Dkt. No. 035394-0286

*usIN THE UNITED STATES PATENT AND TRADEMARK OFFICE*

Applicant: Irina A. BUHIMSCHI et al.  
Title: *NON-INVASIVE ASSESSMENT OF INTRA-AMNIOTIC ENVIRONMENT*  
Appl. No.: 10/541,793  
International Filing Date: 11/13/2003  
371(c) Date: 04/24/2006  
Examiner: Lisa V. Cook  
Art Unit: 1641  
Confirmation Number: 4143

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,


Date 10 May 2007

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

 Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: May 10, 2007 (use as many sheets as necessary)		<b>Complete if Known</b>	
1		of 1	
Application Number		10/541,793	
Filing Date		11/13/2003	
First Named Inventor		Irina A. BUHIMSCHI	
Art Unit		1641	
Examiner Name		Lisa V. Cook	
Attorney Docket Number		035394-0286	

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	B1	I. PHOCAS et al., "Vaginal fluid prolactin: a reliable marker for the diagnosis of prematurely ruptured membranes. Comparison with vaginal fluid alpha-fetoprotein and placental lactogen", EUROPEAN JOURNAL OF OBSTETRICS, GYNECOLOGY, & REPRODUCTIVE BIOLOGY, May 1989, vol. 31, no. 2, May 1989, pp. 133-141.	
	B2	Tatsuro KISHIDA et al., "Persistent detection of alfa-fetoprotein in the vagina without overt preterm premature rupture of the membranes: Clinical and chemical characterizations", Fetal Diagnosis and Therapy, vol. 16, no. 5, September 2001, pp. 259-264.	
	B3	DATABASE EMBASE [Online] ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL 1975, R G SUTCLIFFE, "The nature and origin of the soluble protein in human amniotic fluid", XP002411748, Database accession no. EMB-1976061454 *abstract** & BIOLOGICAL REVIEWS OF THE CAMBRIDGE PHILOSOPHICAL SOCIETY 1975, vol. 50, no. 1, 1975, pp. 1-33.	
	B4	P. TOTH et al., "Alpha-fetoprotein in vaginal fluids. The early diagnosis of premature rupture of membranes.", ACTA PAEDIATRICA HUNGARICA. 1990, vol. 30, no. 3-4, 1990, pp. 399-402, XP008071871 ISSN: 0001-6527 *Abstract.	
	B5	IRINA BUHIMSCHI et al., "Proteomic analysis of preterm parturition: A novel method of identifying the patient at risk of impending preterm delivery." AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, vol. 187, no. 6, Supplement, December 2002, pp. S55, XP008069517 & 23 <sup>rd</sup> ANNUAL MEETING OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE; SAN FRANCISCO, CA, USA; FEBRUARY 3-8, 2003, ISSN: 0002-9378 *abstract*.	
	B6	Irina BUHIMSCHI et al., "Differential antioxidant capacity of amniotic fluid and fetal blood: Implications for understanding pPROM." AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, vol. 187, no. 6 Supplement, December 2002, pp. S237, XP008069521 & 23 <sup>rd</sup> ANNUAL MEETING OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE; SAN FRANCISCO, CA, USA; FEBRUARY 03-08, 2003, ISSN: 0002-9378 *abstract*.	
	B7	Irina BUHIMSCHI et al., "Evidence of free radical formation in preterm labor and preterm PROM", AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY, vol. 187, no. 6 Supplement, December 2002, pg. S238, XP008069518 & 23 <sup>rd</sup> ANNUAL MEETING OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE; SAN FRANCISCO, CA, USA, FEBRUARY 03-08, 2003, ISSN: 0002-9378 *abstract*.	
	B8	M M MUSSAP et al., "Amniotic fluid levels of cystatin C at different gestational ages: A preliminary report", CLINICAL CHEMISTRY AND LABORATORY MEDICINE, vol. 37, no. SPEC. SUPPL. June 1999, pp. S523, XP008071870 & IFC-WORLDBLAD INTERNATIONAL FEDERATION OF CLINICAL AND LABORATORY MEDICINE (17 <sup>th</sup> INTERNATIONAL AND 1; FLORENCE ITALY, JUNE 6-11, 1999, ISSN: 1434-6621 *abstract*.	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.